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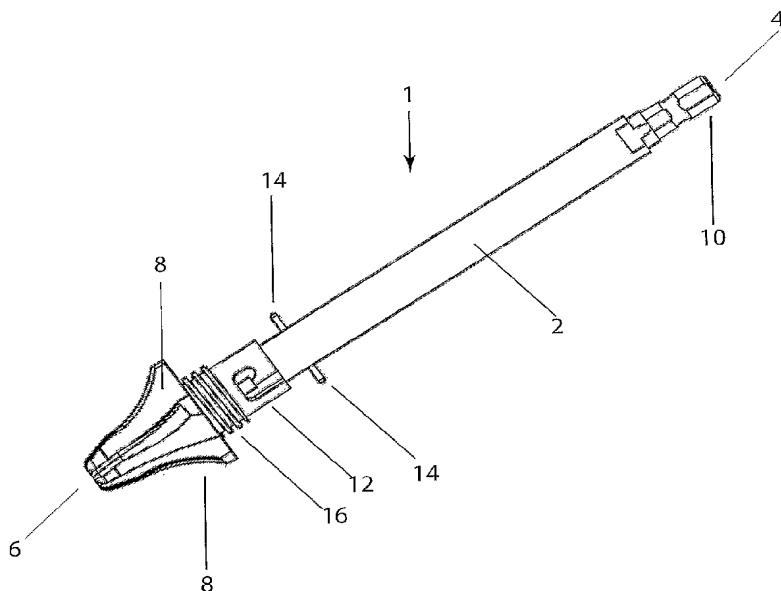
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(57) Abstract: A cutting tool (1) for cutting bone, comprising: a body (2) having a proximal end (4) and a distal end (6); and at least one primary cutting surface (8) disposed at the distal end (6); wherein the at least one primary cutting surface (8) is shaped so that when, in use, a torque is applied to the proximal end (4) of the body (2), the at least one primary cutting surface (8) cuts a conical or frustoconical shaped cavity in the bone. A method for cutting bone using such a cutting tool (1).



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MEDICAL DEVICES

This invention relates to medical devices, and in particular cutting tools and alignment devices for cutting bone, especially the femur.

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Hip replacements involve the use of an implant stem which is fitted into the medullary canal of the femur. GB 2388321 discloses a particularly effective femoral implant comprising a femoral head at a proximal end thereof, a stem part extending to a distal end of the implant, and a section from which the stem part extends. Said section has an external surface of frustoconical or substantially frustoconical form and it tapers towards said stem part and away from said femoral head. Said femoral head extends directly away from said section to the proximal end of the implant. Said section includes a base portion, at its maximum diameter, which extends substantially axially away from, and is substantially the same diameter as, the end surface of the resected head into which said stem is to be inserted, in use. GB 2388321 also discloses a particularly effective femoral implant stem having the above features without the femoral head. The stem part may be curved or straight.

20 In the Hip replacement operation using the above femoral implant, the proximal end of the femur is resected and a frustoconical or generally frustoconical shaped cavity is then produced at the upper end of the medullary canal by machining, for example milling. Milling is achieved by using conventional cutting tools such as reamers.

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However, producing a frustoconical or generally frustoconical shaped cavity corresponding to the dimensions of the above femoral implants is difficult with conventional cutting tools. The procedure can take several attempts and bone may be damaged. The cavity, particularly the upper end, is often undersized or oversized with respect to the size of the femoral implant. In addition, the cutting tool may be misaligned with the optimal cutting axis. Furthermore, the cutting tool may over-shoot the correct end-point. Consequently, the selected femoral implant does not mate with the cavity properly, leading to instability and/or bone damage.

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It is therefore an aim of the present invention to provide a cutting tool and an alignment device that overcomes the above problems.

5 According to a first aspect of the present invention, there is provided a cutting tool for cutting bone, comprising:

a body having a proximal end and a distal end; and

at least one primary cutting surface disposed at the distal end;

10 wherein the primary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

In this application, a conical or frustoconical shaped cavity includes cavities that are generally (substantially) conical or frustoconical shaped. A

15 frustoconical shaped cavity is a truncated cone shape. The cone or frustum may have straight, substantially straight, curved or substantially curved sides.

The present invention has the advantage that it provides a cutting tool that enables the surgeon to accurately cut a conical or frustoconical shaped cavity
20 in the bone.

The cutting tool may comprise one primary cutting surface disposed at the distal end of the body.

25 The cutting tool may comprise a plurality of primary cutting surfaces disposed at the distal end of the body. The cutting tool may comprise two to twenty cutting surfaces. The cutting tool may comprise two to ten cutting surfaces.

The cutting tool may comprise two, three, four, five, six, or seven cutting surfaces. Preferably, the cutting tool comprises three to six cutting surfaces.

30 More preferably, the cutting tool comprises five cutting surfaces.

The primary cutting surfaces may be disposed equidistantly about the main axis of the body.

The conical section of the primary cutting surfaces may consist of a cone shape. The cone may be formed by a radius of approximately 10-100 mm. Preferably, the cone is formed by a radius of approximately 15-60 mm.

- 5 The at least one primary cutting surface may be a cutting tooth. The or each cutting tooth may be fluted. The or each fluted cutting tooth may have a curved cutting edge. The or each fluted cutting tooth may have a linear cutting edge.
- 10 The or each cutting tooth may have an average tooth depth of 0.5-10 mm. Preferably, the or each cutting tooth has an average tooth depth of 0.5-4 mm. The or each cutting edge may have a length of 5-200 mm. Preferably, the or each cutting edge has a length of 15-50 mm.
- 15 According to embodiments of the present invention, the cutting tool further comprises at least one secondary cutting surface disposed distally to the at least one primary cutting surface, wherein the secondary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the secondary cutting surface cuts a conical or frustoconical shaped
- 20 cavity in the bone.

- Such embodiments of the invention have the advantage that they enable a surgeon to accurately cut a first conical or frustoconical shaped cavity with the at least one secondary cutting surface and then a second conical or
- 25 frustoconical shaped cavity with the at least one primary cutting surface in a single procedure using a single tool.

The cutting tool may comprise one secondary cutting surface.

- 30 The cutting tool may comprise a plurality of secondary cutting surfaces. The cutting tool may comprise two to twenty cutting surfaces. The cutting tool may comprise two to ten cutting surfaces. The cutting tool may comprise two, three, four, five, six, or seven cutting surfaces. Preferably, the cutting tool

comprises three to six cutting surfaces. More preferably, the cutting tool comprises five cutting surfaces.

5 The secondary cutting surfaces may be disposed equidistantly about the main axis of the body.

The conical section of the secondary cutting surfaces may consist of a cone shape. The cone may be formed by a radius of approximately 10-100 mm. Preferably, the cone is formed by a radius of approximately 15-60 mm.

10 The at least one secondary cutting surface may be a cutting tooth. The or each cutting tooth may be fluted. The or each fluted cutting tooth may have a curved cutting edge. The or each fluted cutting tooth may have a linear cutting edge.

15 The or each cutting tooth may have an average tooth depth of 0.5-10 mm. Preferably, the or each cutting tooth has an average tooth depth of 0.5-4 mm. The or each cutting edge may have a length of 5-200 mm. Preferably, the or each cutting edge has a length of 15-50 mm.

20 The following features apply to embodiments according to the first aspect or the second aspect of the invention.

25 The proximal end of the body may have a means for releasably connecting to a rotary power source. The rotary power source may be a drill.

The total length of the cutting tool may be in the range 15-400 mm. The total length may be in the range 120-250 mm. Preferably, the total length is in the range 150-170 mm.

30 The body of the cutting tool may be a shaft. The shaft may be cylindrical. The shaft may be oblong.

The cutting tool may be cannulated. A conduit may extend through the body of the cutting tool. The conduit may extend through the or each primary cutting surface. The conduit may extend through the or each secondary cutting surface. The conduit may be shaped so as to receive a guide rod, in use.

The or each primary cutting surface may be disposed off axis with respect to the conduit axis so that they do not interfere with the guide rod that is received by the conduit. The or each secondary cutting surface may be disposed off axis with respect to the conduit axis so that they do not interfere with the guide rod that is received by the conduit.

The conduit may have a diameter in the range 2-20 mm. The conduit may have a diameter in the range 4-10 mm. Preferably, the conduit has a diameter in the range 5-6 mm.

The cutting tool may comprise a means for attaching to an alignment device.

The cutting tool may be made of a single material. The cutting tool may be made of two or more materials. The cutting tool may be made of a plastic material. The cutting tool may be made of metal. The metal may be titanium. The metal may be stainless steel. The cutting tool may be made of an alloy.

The bone may be a femur. The femur may be resected.

According to a second aspect of the present invention, there is provided a device for aligning a cutting tool with a bone, comprising:

a body having an internal surface and an external surface, the internal surface being shaped so as to accommodate, in use, a cutting tool and the end of a bone,

the body having a proximal end and a distal end, the proximal end having an attachment means for releasably attaching, in use, the cutting tool, wherein, in use, the cutting tool is releasably attached to the attachment means and the body engages the end of the bone such that the

cutting tool is aligned with the bone and the cutting depth of the cutting tool is limited.

- 5 The alignment device of the present invention has the advantage that it aligns the cutting tool with the optimal cutting axis and it prevents the cutting tool from over-shooting the correct end-point.

- 10 The body may be a cylinder, the distal end of the cylinder being open and the proximal end being partially closed such that it can engage, in use, the end of the bone.

The cylinder may have continuous sides.

- 15 The cylinder may have castellated sides.

The body may have a diameter in the range 10-100 mm. The body may have a diameter in the range 20-70 mm. The body may have a length in the range 10-200 mm. The body may have a length in the range 20-40 mm.

- 20 The internal surface may have at least one projection disposed perpendicular or substantially perpendicular to the majority of the internal surface, wherein, in use, the at least one projection engages with the end of the bone, thereby limiting the cutting depth of the cutting tool.

- 25 The at least one projection may be disposed near to the proximal end of the body. The at least one projection may be disposed near to the distal end of the body. The at least one projection may be disposed near to the mid-point between the proximal and distal ends of the body.

- 30 The at least one projection may be a single post or the like. The at least one projection may be a plurality of posts or the like.

The at least one projection may be a ledge. The ledge may be continuous, extending around the internal surface.

The at least one projection may be a plurality of ledges spaced around the internal surface.

- 5 The attachment means may comprise a bayonet fitting which engages, in use, with at least one corresponding lug on the cutting tool.

The attachment means may comprise at least one spring-loaded ball bearing that releasably engages, in use, with a corresponding recess in the cutting
10 tool.

The alignment device may be made of a single material. The alignment device may be made of two or more materials. The alignment device may be made of a plastic material. The alignment device may be made of metal. The
15 metal may be titanium. The metal may be stainless steel. The alignment device may be made of an alloy.

The bone may be a femur. The femur may be resected.

- 20 According to a third aspect of the present invention, there is provided an apparatus for cutting bone, comprising a cutting tool according to the first aspect of the present invention in combination with a device according to the second aspect of the present invention.

- 25 The device may be releasably attached to the cutting tool. The device may be fixedly attached to the cutting tool.

The apparatus may be made of a single material. The apparatus may be made of two or more materials. The apparatus may be made of a plastic
30 material. The apparatus may be made of metal. The metal may be titanium. The metal may be stainless steel. The apparatus may be made of an alloy.

According to a fourth aspect of the present invention, there is provided a system for cutting bone, comprising:

at least one cutting tool according to the first aspect of the present invention; and

at least one device according to the second aspect of the present invention.

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The system may comprise a plurality of cutting tools. The cutting tools may differ in the number of primary and/or secondary cutting surfaces. The cutting tools may differ in the shape of the primary and/or secondary cutting surfaces. The system may comprise a plurality of devices.

10

A surgeon can select appropriate cutting tools and alignment devices according to the various embodiments of the invention as hereinbefore described depending on his/her particular requirements.

15 According to a fifth aspect of the present invention, there is provided a method for cutting bone, comprising:

preparing a resected bone;

20 providing a cutting tool, the cutting tool comprising a body having a proximal end and a distal end, and at least one primary cutting surface disposed at the distal end, wherein the at least one primary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone; and

25 applying a torque to the proximal end of the body so that the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

According to embodiments of the present invention, the method of the fifth aspect of the present invention may further comprise:

30 providing a second cutting tool, the second cutting tool comprising a body having a proximal end and a distal end, and at least one primary cutting surface disposed at the distal end, wherein the at least one primary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the at least one primary cutting surface cuts a conical or

frustoconical shaped cavity in the bone, the second cutting tool further comprising at least one secondary cutting surface disposed distally to the at least one primary cutting surface, wherein the at least one secondary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in the bone; and

applying a torque to the proximal end of the body of the second cutting tool so that the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

Thus, the surgeon can prepare a first conical or frustoconical shaped cavity in the bone using the cutting tool of the fifth aspect. The surgeon may then use a second cutting tool to prepare a second conical or frustoconical shaped cavity distal to the first cavity. The surgeon may continue cutting with the second cutting tool so that the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

According to a sixth aspect of the present invention, there is provided a method for cutting bone, comprising:

preparing a resected bone;
providing a cutting tool, the cutting tool comprising a body having a proximal end and a distal end, and at least one primary cutting surface disposed at the distal end, wherein the at least one primary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone, the cutting tool further comprising at least one secondary cutting surface disposed distally to the at least one primary cutting surface, wherein the at least one secondary cutting surface is shaped so that when, in use, a torque is applied to the proximal end of the body, the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in the bone; and

applying a torque to the proximal end of the body so that the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in

the bone before the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

Thus, the surgeon can accurately cut a first conical or frustoconical shaped cavity with the at least one secondary cutting surface and then a second
5 conical or frustoconical shaped cavity with the at least one primary cutting surface in a single procedure using a single tool.

According to embodiments of the present invention, the methods of the fifth or
10 sixth aspects of the present invention may further comprise:

- inserting a guide bar in the resected bone;
- providing a cutting tool according to the first aspect of the present invention that is cannulated;
- passing the cutting tool down over the guide bar; and
15 cutting the bone.

Thus, the surgeon can use cannulated cutting tools according to the first aspect of the present invention. This has the advantage that the alignment of the cutting tool is optimised.
20

According to embodiments of the present invention, the methods of the fifth or sixth aspects of the present invention may further comprise:

- providing a cutting tool according to the first aspect of the present invention comprising a means for attaching to an alignment device.
- 25 providing an alignment device according to the second aspect of the present invention;
- attaching the alignment device to the cutting tool; and
- cutting the bone.

30 Thus, the surgeon can use a cutting tool according to the first aspect of the present invention with an alignment device according to the second aspect of the present invention. This has the advantage that the alignment of the cutting tool is optimised and over-shooting is prevented. The surgeon may also use a guide bar as described above to optimise alignment.

The methods of the fifth or sixth aspects of the present invention may include cutting tools having any of the features of the first aspect of the present invention as hereinbefore described. The methods of the fifth or sixth aspects
5 of the present invention may include alignment devices having any of the features of the second aspect of the present invention as hereinbefore described.

According to a seventh aspect of the present invention, there is provided a
10 method for cutting bone, comprising:

preparing a resected bone;
providing an apparatus, the apparatus comprising a cutting tool according to the first aspect of the present invention in combination with a device according to the second aspect of the present invention; and
15 applying a torque to the proximal end of the body so that the at least one primary and/or the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in the bone.

In the methods of the fifth, sixth or seventh aspects of the present invention,
20 the bone may be a femur.

Reference will now be made, by way of example, to the accompanying drawings, in which:

25 Figure 1 shows a side view of a cutting tool according to an embodiment of the present invention;

Figure 2 shows a side view of a cutting tool according to an embodiment of the present invention;

30 Figure 3 shows a side view of a cutting tool according to an embodiment of the present invention;

Figure 4 shows a perspective view of an alignment device according to an embodiment of the present invention;

Figure 5 shows a top plan view of the alignment device of Figure 4;

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Figure 6 shows a side view of the alignment device of Figure 4;

Figure 7 shows a cross-section of a cutting tool according to an embodiment of the present invention in combination with an alignment device according to an embodiment of the present invention;

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Figure 8 shows a side view of a cutting tool according to an embodiment of the present invention in combination with an alignment device according to an embodiment of the present invention;

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Figure 9 shows a perspective view of a cutting tool according to an embodiment of the present invention in combination with an alignment device according to an embodiment of the present invention, in use cutting a femur;

Figure 10 shows a perspective view of a cutting tool according to an embodiment of the present invention in combination with an alignment device according to an embodiment of the present invention, in use cutting a femur;

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Figure 11 shows a perspective view of a femur having a prepared cavity;

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Figure 12 shows a perspective view of a stem implant being inserted into the cavity of the femur of Figure 11;

Figure 13 shows a perspective view of a femur having the stem implant of Figure 12 implanted; and

30

Figure 14 shows a femur fitted with a femoral implant.

Figure 1 shows a side view of a cutting tool (1) according to an embodiment of the present invention. The cutting tool comprises a body (2) in the form of a shaft (2) having a proximal end (4) and a distal end (6). Five (only three are shown) primary cutting surfaces (8) in the form of fluted teeth are disposed at the distal end (6) of the shaft (2). The cutting surfaces are disposed equidistantly about the main axis of the shaft (2). The primary cutting surfaces are shaped so that when a torque is applied to the proximal end (4) of the shaft (2), the primary cutting surfaces cut a frustoconical or substantially frustoconical shaped cavity in the bone.

The conical section of the primary cutting surfaces (8) consists of a cone shape. The cone is formed by a radius of approximately 15 to 60 mm. The proximal end diameter of the cone can range between approximately 15-60 mm. Preferably, the diameter ranges between approximately 25-45 mm.

The five fluted teeth (8) extend the full length of the cone with an average tooth depth of approximately 1.5-3.5 mm, preferably around 3 mm. The tooth form flows out of the proximal end of the cone to allow debris to escape.

In an alternative embodiment of the invention (not shown), the primary cutting surfaces are shaped so that when a torque is applied to the proximal end (4) of the shaft (2), the primary cutting surfaces cut a conical or substantially conical shaped cavity in the bone.

The proximal end (4) of the shaft (2) has a means (10) for reversibly connecting to a power source (not shown). The connection means (10) may be a standard drive connection for releasable connection to a power drill source or the like.

The cutting tool (1) has a means (12) for releasably attaching an alignment device (52), such as that shown in Figures 4 to 10. The attachment means (12) comprises two male lugs (14) attached to the shaft (2) proximal to the cutting surfaces (8). The male lugs (14) engage with corresponding L-shaped grooves (74) in the alignment device (52) (see Figures 7 and 8). The

attachment means also comprises a spring (16) attached to the shaft proximal and adjacent to the cutting surfaces (8). When the alignment device (52) is attached to the cutting tool (1) the spring is put under load and the tension of the spring releasably locks the alignment device (52) in position.

5

In an alternative embodiment of the invention (not shown), the attachment means comprises corresponding threads located on the shaft of the cutting tool (proximal to the cutting surfaces) and the alignment device.

10 The shaft (2) has a length of approximately 80-200 mm measured between the proximal end of the attachment means (12) and the distal end of the connection means (10). The shaft (2) diameter may be approximately 5-15 mm along this length.

15 The whole length of the cutting tool (1) can be cannulated in order to accommodate a guide rod, in use. The average cannulation diameter may be 4-10 mm, preferably 5-6 mm.

Figure 2 shows a side view of a cutting tool (20) according to another
20 embodiment of the present invention. The cutting tool (20) comprises a body (22) in the form of a shaft (22) having a proximal end (24) and a distal end (26). Five (only two are shown) primary cutting surfaces (28) in the form of angled teeth are disposed at the distal end (26) of the shaft (22). The primary cutting surfaces (28) are disposed equidistantly about the main axis of the
25 shaft (22). The cutting tool also comprises five (only two are shown) secondary cutting surfaces (30) in the form of angled teeth disposed distally to the primary cutting surfaces (28). The secondary cutting surfaces (30) are disposed equidistantly about the main axis of the shaft (22).

30 The primary cutting surfaces (28) and the secondary cutting surfaces (30) together form the first (32) and second (34) parts, respectively, of a tapered portion (36). The first part (32) of the tapered portion (36) may have an inclusive angle of approximately 10 to 35 degrees depending on the size of the cutting tool (20). The taper length of the first part (32) may be

approximately 5 to 40 mm, preferably 5 to 20 mm, depending on the size of the cutting tool (20). The second part (34) of the tapered portion (36) may have an inclusive angle of approximately 2 to 10 degrees, preferably 3 to 5 degrees depending on the size of the cutting tool (20). The taper length of the
5 second part (32) may be approximately 30 to 100 mm, preferably 50 to 70 mm, depending on the size of the cutting tool (20). The average tooth depth along the length of the tapered portion (36) may be approximately 1.5-3.5 mm, preferably 3 mm. The tooth form of the cutting surfaces (28,30) flows out of the proximal end of the tapered portion (36) enabling debris to escape.

10 The primary (28) and secondary (30) cutting surfaces are shaped so that when a torque is applied to the proximal end (24) of the shaft (22), the primary (28) and secondary (30) cutting surfaces cut a frustoconical or substantially frustoconical shaped cavity in the bone.

15 In an alternative embodiment of the invention (not shown), the secondary cutting surfaces are shaped so that when a torque is applied to the proximal end (4) of the shaft (2), the secondary cutting surfaces cut a conical or substantially conical shaped cavity in the bone.

20 The proximal end (24) of the shaft (22) has a means (38) for reversibly connecting to a power source (not shown). The connection means (38) may be a standard drive connection for releasable connection to a power drill source or the like.

25 The cutting tool (20) has a means (40) for releasably attaching an alignment device (52), such as that shown in Figures 4 to 8. The attachment means (40) comprises two male lugs (42) attached to the shaft (22) proximal to the primary cutting surfaces (28). The male lugs (42) engage with corresponding
30 L-shaped grooves (74) in the alignment device (52). The attachment means (40) also comprises a spring (44) attached to the shaft (22) proximal and adjacent to the cutting surfaces (28). When the alignment device (52) is attached to the cutting tool (20) the spring (44) is put under load and the tension of the spring releasably locks the alignment device (52) in position.

In an alternative embodiment of the invention (not shown), the attachment means comprises corresponding threads located on the shaft of the cutting tool (proximal to the cutting surfaces) and the alignment device.

5

The shaft (22) has a length of approximately 80-200 mm measured between the proximal end of the attachment means (40) and the distal end of the connection means (38). The shaft (22) diameter may be approximately 5-15 mm along this length.

10

The whole length of the cutting tool (20) can be cannulated in order to accommodate a guide rod, in use. The average cannulation diameter may be 4 to 10 mm, preferably 5 to 6 mm.

15 Figure 3 shows a side view of a cutting tool (30) according to another embodiment of the present invention. The cutting tool (30) combines some of the features of the cutting tools (1, 20) of figures 1 and 2.

The cutting tool (30) comprises a body (32) in the form of a shaft (32) having a proximal end (34) and a distal end (36). Five (only three are shown) primary cutting surfaces (38) in the form of fluted teeth are disposed at the distal end (36) of the shaft (32). The cutting surfaces are disposed equidistantly about the main axis of the shaft (32). The primary cutting surfaces are shaped so that when a torque is applied to the proximal end (34) of the shaft (32), the primary cutting surfaces cut a frustoconical or substantially frustoconical shaped cavity in the bone. The cutting tool also comprises five (only three are shown) secondary cutting surfaces (40) in the form of angled teeth disposed distally to the primary cutting surfaces (38). The secondary cutting surfaces (40) are disposed equidistantly about the main axis of the shaft (32).

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The conical section of the primary cutting surfaces (38) consists of a cone shape. The cone is formed by a radius of approximately 15 to 60 mm. The proximal end diameter of the cone can range between approximately 15-60 mm. Preferably, the diameter ranges between approximately 25-45 mm. The

distal end of the cone tapers inwards to a diameter of approximately 10 to 15 mm, preferably approximately 8 to 13 mm. At this point the secondary cutting surfaces (40) extend distally.

- 5 The five fluted teeth (38) extend the full length of the cone with an average tooth depth of approximately 1.5-3.5 mm, preferably 3 mm. The tooth form flows out of the proximal end of the cone to allow debris to escape.

- 10 The secondary cutting surfaces (40) form a tapered portion (42) which may have an inclusive angle of approximately 2 to 10 degrees, preferably approximately 3 to 5 degrees, depending on the size of the cutting tool (30). The taper length of the tapered portion (42) may be approximately 30 to 100 mm, preferably approximately 50 to 70 mm, depending on the size of the cutting tool (30). The tooth form of the cutting surfaces (40) flows out of the proximal end of the tapered portion (42) enabling debris to escape.

- 15 The primary (38) and secondary (40) cutting surfaces are shaped so that when a torque is applied to the proximal end (34) of the shaft (32), the primary (38) and secondary (40) cutting surfaces cut a frustoconical or substantially frustoconical shaped cavity in the bone.

- 20 In an alternative embodiment of the invention (not shown), the secondary cutting surfaces are shaped so that when a torque is applied to the proximal end (34) of the shaft (32), the secondary cutting surfaces cut a conical or substantially conical shaped cavity in the bone.

- 25 The proximal end (34) of the shaft (32) has a means (44) for reversibly connecting to a power source (not shown). The connection means (44) may be a standard drive connection for releasable connection to a power drill source or the like.

30 The cutting tool (30) has a means (46) for releasably attaching an alignment device (52), such as that shown in Figures 4 to 8. The attachment means (46) comprises two male lugs (48) attached to the shaft (32) proximal to the

primary cutting surfaces (38). The male lugs (48) engage with corresponding L-shaped grooves (74) in the alignment device (52). The attachment means (46) also comprises a spring (50) attached to the shaft (32) proximal and adjacent to the cutting surfaces (38). When the alignment device (52) is
5 attached to the cutting tool (30) the spring (50) is put under load and the tension of the spring releasably locks the alignment device (52) in position.

In an alternative embodiment of the invention (not shown), the attachment means comprises corresponding threads located on the shaft of the cutting
10 tool (proximal to the cutting surfaces) and the alignment device.

The shaft (32) has a minimum length of approximately 80-200 mm measured between the proximal end of the attachment means (46) and the distal end of the connection means (44). The shaft (32) diameter may be approximately 5-
15 15 mm along this length.

The whole length of the cutting tool (30) can be cannulated in order to accommodate a guide rod, in use. The average cannulation diameter may be approximately 4-10 mm, preferably 5-6 mm.

20 Figures 4 to 6 show various views of a device (52) for aligning a cutting tool with a bone according to an embodiment of the present invention. The device comprises a cylindrical body (54) having an internal surface (56) and an external surface (58). The body (54) has a proximal end (60) and a distal end (62). In use, the internal surface (56) can accommodate a cutting tool and the
25 end of a bone (see figures 7 to 10).

The internal surface (56) is recessed towards the distal end (62) and the resulting ledge/flat edge (64) which extends around and is substantially
30 perpendicular to the internal surface (56) acts as a stop when it comes into contact with the end of the bone, thereby limiting the cutting depth of the cutting tool.

The proximal end (60) of the body (54) has an attachment means (66) for releasably attaching a cutting tool, as exemplified in figures 7 and 8. The attachment means (66) comprises an open cylinder (68) that is connected to the internal surface (56) of the proximal end (60) of the body (54) by three
5 arms (70) which are equidistantly spaced around the periphery of the open cylinder (68). The three open spaces (72) formed between the three arms (70) enable debris to flow out of the cutting tool. The open cylinder (68) has two L-shaped recesses (74) that, in use, mate with male lugs on the cutting tool in a bayonet fitting (see Figure 7 and 8). The cutting tool can therefore be
10 releasably attached to the alignment device (52).

As shown in Figure 7, the attachment means (46) also comprises a spring (50) attached to the shaft (32) proximal and adjacent to the primary cutting surfaces (38). When the alignment device (52) is attached to the cutting tool
15 (30) the spring (50) is put under load and the tension of the spring releasably locks the alignment device (52) in position such that the male lugs are prevented from accidentally slipping out of the L-shaped recesses (74) during use.

20 Figures 9 to 14 show various stages of a mid head resection hip replacement operation using devices according to the present invention. As shown in Figure 9, a combined cutting tool (1) and alignment device (52) as shown in Figure 8 is selected, with the alignment device (52) having dimensions complementary to the dimensions of the resected femoral head (80). The
25 combined cutting tool (1) and alignment device (52) assembly is aligned with the guide rod (76) and the conduit/bore of the cutting tool receives the guide rod (76). The assembly is passed down over the guide rod and a rotary power source such as a drill (not shown) is activated such that a torque is applied to the proximal end of the shaft (2). Consequently, the primary cutting
30 surfaces (8) cut a frustoconical shaped cavity in the bone. The cutting operation is continued until the proximal end of the femur makes contact with and is stopped by the ledge/flat edge (64) of the internal surface (56) of the alignment device (52), thereby limiting the cutting depth of the cutting tool (1). The assembly is then removed from the guide rod (76).

- The alignment device (52) is removed from the cutting tool (1) and attached to the cutting tool (20), as shown in Figure 10. The combined cutting tool (20) and alignment device (52) assembly is aligned with the guide rod (76) and the conduit/bore of the cutting tool receives the guide rod (76). The assembly is passed down over the guide rod and a rotary power source such as a drill (not shown) is activated such that a torque is applied to the proximal end of the shaft (22). Consequently, the secondary cutting surfaces (30) cut a further, narrower frustoconical shaped cavity in the bone. The cutting operation is continued until the proximal end of the femur makes contact with and is stopped by the ledge/flat edge (64) of the internal surface (56) of the alignment device (52), thereby limiting the cutting depth of the cutting tool (20). The assembly is then removed from the guide rod (76).
- The resulting cavity prepared in the medullary canal of the resected proximal end of the femur is shown in Figure 11. The cavity has a proximal frustoconical shaped cavity (82) which is continuous with a distal frustoconical shaped cavity (84). Figure 12 shows a femoral stem implant (90) being inserted into the femoral head cavity (82, 84) using a stem introducer (92).
- Figure 13 shows the stem implant (90) implanted in the femoral head (80). Figure 14 shows an implant femoral head (94) attached to the stem implant (90).

CLAIMS

1. A cutting tool for cutting bone, comprising:
a body having a proximal end and a distal end; and
5 at least one primary cutting surface disposed at the distal end;
wherein the at least one primary cutting surface is shaped so that
when, in use, a torque is applied to the proximal end of the body, the at least
one primary cutting surface cuts a conical or frustoconical shaped cavity in the
bone.
10
2. A cutting tool according to claim 1, comprising a plurality of primary
cutting surfaces disposed at the distal end of the body.
3. A cutting tool according to claim 2, wherein the primary cutting surfaces
15 are disposed equidistantly about the main axis of the body.
4. A cutting tool according to any preceding claim, wherein the at least
one primary cutting surface is a cutting tooth.
- 20 5. A cutting tool according to claim 4, wherein the or each cutting tooth is
fluted.
6. A cutting tool according to any preceding claim, further comprising at
least one secondary cutting surface disposed distally to the at least one
25 primary cutting surface, wherein the at least one secondary cutting surface is
shaped so that when, in use, a torque is applied to the proximal end of the
body, the at least one secondary cutting surface cuts a conical or frustoconical
shaped cavity in the bone.
- 30 7. A cutting tool according to claim 6, comprising a plurality of secondary
cutting surfaces.
8. A cutting tool according to claim 7, wherein the secondary cutting
surfaces are disposed equidistantly about the main axis of the body.

9. A cutting tool according to any of claims 6 to 8, wherein the at least one secondary cutting surface is a cutting tooth.
- 5 10. A cutting tool according to claim 9, wherein the or each cutting tooth is fluted.
11. A cutting tool according to any preceding claim, wherein the proximal end of the body has a means for releasably connecting to a rotary power
10 source.
12. A cutting tool according to claim 11, wherein the rotary power source is a drill.
13. A cutting tool according to any preceding claim, wherein the body is a shaft.
14. A cutting tool according to claim 13, wherein the shaft is cylindrical.
15. A cutting tool according to any preceding claim, wherein the cutting tool is cannulated.
16. A cutting tool according to any preceding claim, further comprising a means for attaching to an alignment device.
17. A cutting tool according to any preceding claim, wherein the bone is a femur.
18. A cutting tool according to claim 17, wherein the femur is resected.
19. A device for aligning a cutting tool with a bone, comprising:
a body having an internal surface and an external surface, the internal surface being shaped so as to accommodate, in use, a cutting tool and the end of a bone,

the body having a proximal end and a distal end, the proximal end having an attachment means for releasably attaching, in use, the cutting tool, wherein, in use, the cutting tool is releasably attached to the attachment means and the body engages the end of the bone such that the cutting tool is aligned with the bone and the cutting depth of the cutting tool is limited.

20. A device according to claim 19, wherein the body is a cylinder, the distal end of the cylinder being open and the proximal end being partially closed such that it can engage, in use, the proximal end of the bone.

21. A device according to claim 19 or 20, wherein the internal surface has at least one projection substantially perpendicular to the majority of the internal surface, and wherein, in use, the at least one projection engages with the proximal end of the bone, thereby limiting the cutting depth of the cutting tool.

22. A device according to claim 21, wherein the at least one projection is a continuous ledge extending around the internal surface.

23. A device according to any of claims 19 to 22, wherein the attachment means comprises a bayonet fitting which engages, in use, with at least one corresponding lug on the cutting tool.

24. A device according to any of claims 19 to 22, wherein the attachment means comprises at least one spring-loaded ball bearing that releasably engages, in use, with a corresponding recess in the cutting tool.

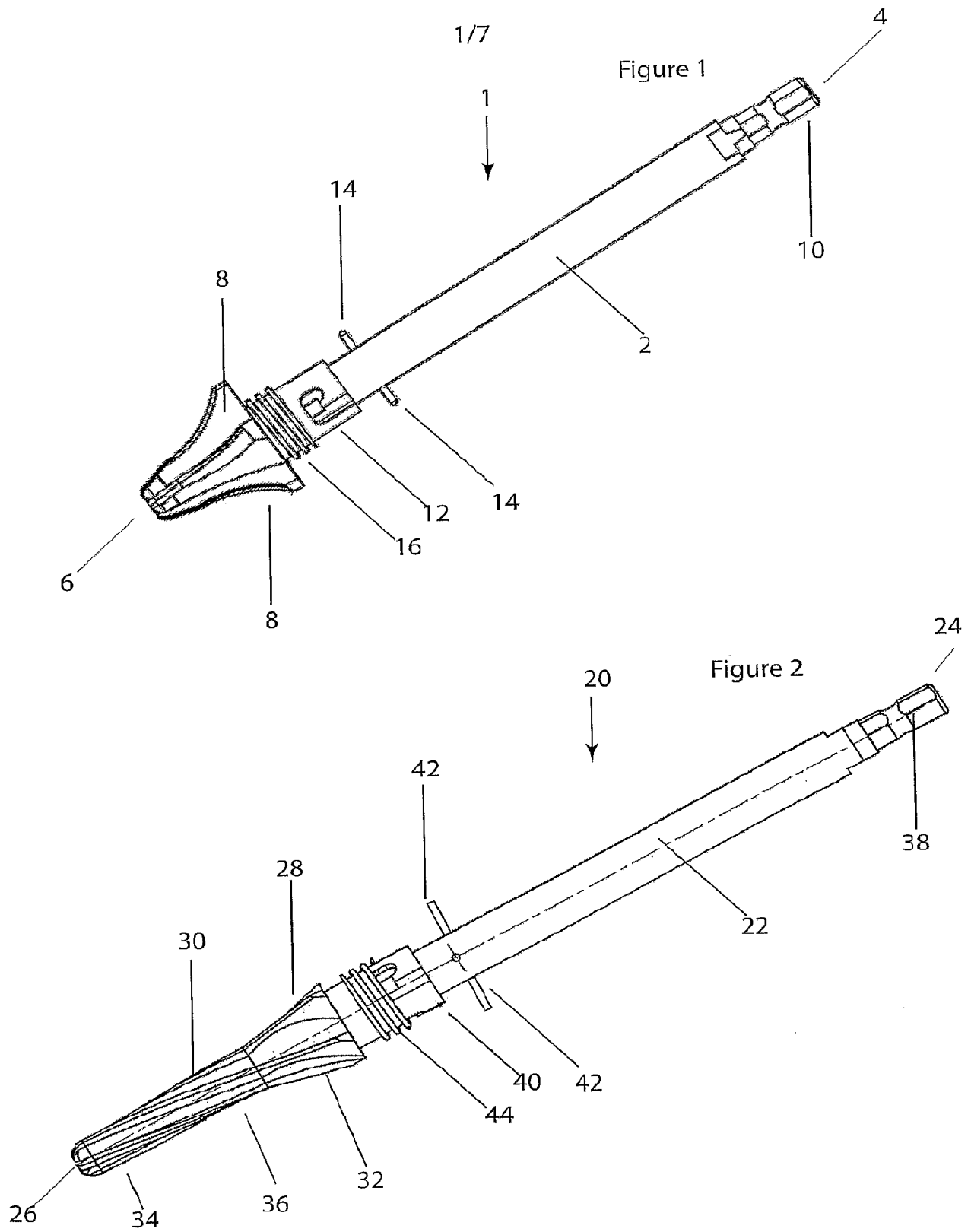
25. A device according to any preceding claim, wherein the bone is a femur.

26. A device according to any preceding claim, wherein the femur is resected.

27. An apparatus for cutting bone, comprising a cutting tool according to any of claims 1 to 18 in combination with a device according to any of claims 19 to 26.
- 5 28. An apparatus according to claim 27, wherein the device is fixedly attached to the cutting tool.
29. A system for cutting bone, comprising:
at least one cutting tool according to any of claims 1 to 18; and
10 at least one device according to any of claims 19 to 26.
30. A method for cutting bone, comprising:
preparing a resected bone;
providing a cutting tool according to any of claims 1 to 5; and
15 applying a torque to the proximal end of the body so that the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.
31. A method according to claim 30, further comprising:
20 providing a second cutting tool according to any of claims 6 to 10; and
applying a torque to the proximal end of the body of the second cutting tool so that the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in the bone.
- 25 32. A method for cutting bone, comprising:
preparing a resected bone;
providing a cutting tool according to any of claims 6 to 10; and
applying a torque to the proximal end of the body so that the at least one secondary cutting surface cuts a conical or frustoconical shaped cavity in
30 the bone before the at least one primary cutting surface cuts a conical or frustoconical shaped cavity in the bone.
33. A method according to any of claims 30 to 32, further comprising providing a cutting tool according to any of claims 11 to 14.

34. A method according to any of claims 30 to 33, further comprising:
inserting a guide bar in the resected bone;
providing a cutting tool according to claim 15;
5 passing the cutting tool down over the guide bar; and
cutting the bone.
35. A method according to any of claims 30 to 34, further comprising:
providing a cutting tool according to claim 16.
10 providing an alignment device according to any of claims 19 to 24;
attaching the alignment device to the cutting tool; and
cutting the bone.
36. A method for cutting bone, comprising:
15 preparing a resected bone;
providing an apparatus according to claim 28; and
applying a torque to the proximal end of the body so that the at least
one primary and/or the at least one secondary cutting surface cuts a conical
or frustoconical shaped cavity in the bone.
20
37. A method according to any of claims 30 to 36, wherein the bone is a
femur.
38. A cutting tool substantially as hereinbefore described with reference to
25 the accompanying drawings.
39. An alignment device substantially as hereinbefore described with
reference to the accompanying drawings.
- 30 40. An apparatus substantially as hereinbefore described with reference to
the accompanying drawings.
41. A system substantially as hereinbefore described with reference to the
accompanying drawings.

42. A method substantially as hereinbefore described with reference to the accompanying drawings.



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Figure 3

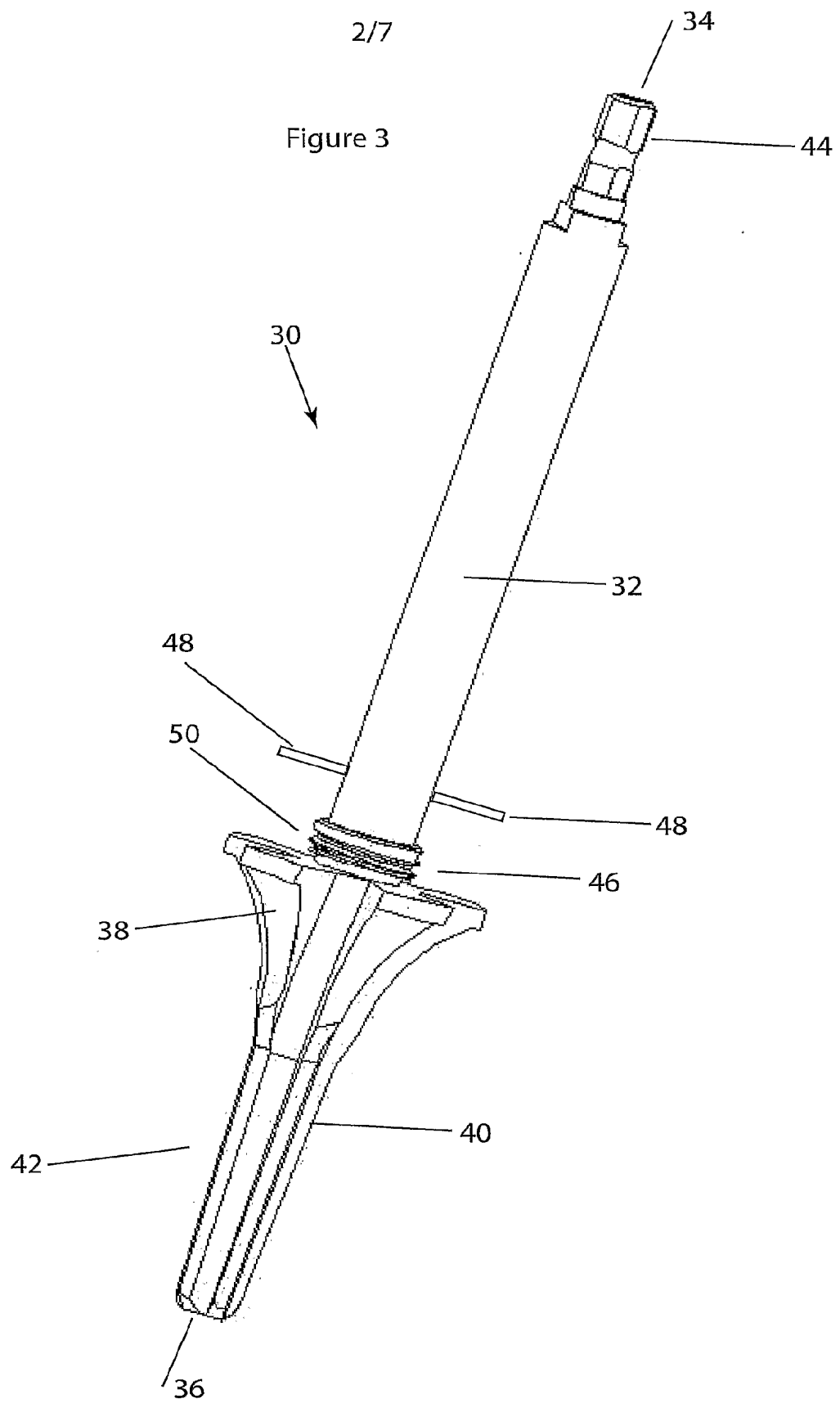
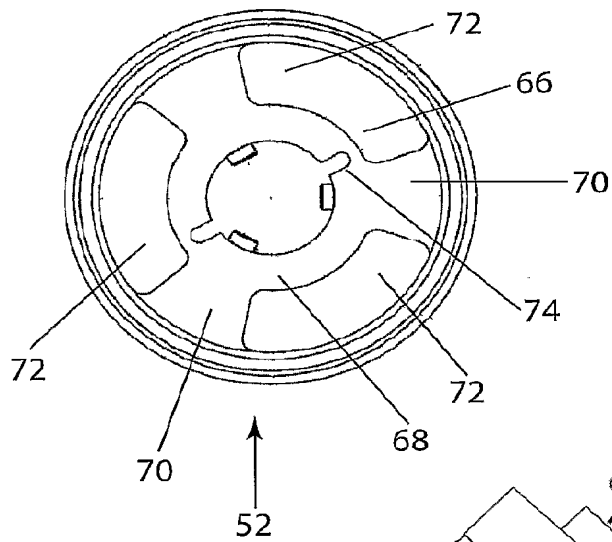


Figure 5



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Figure 8

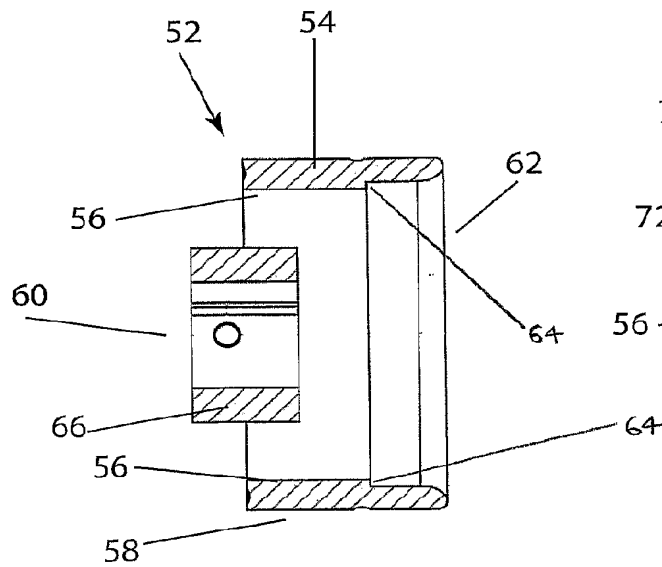
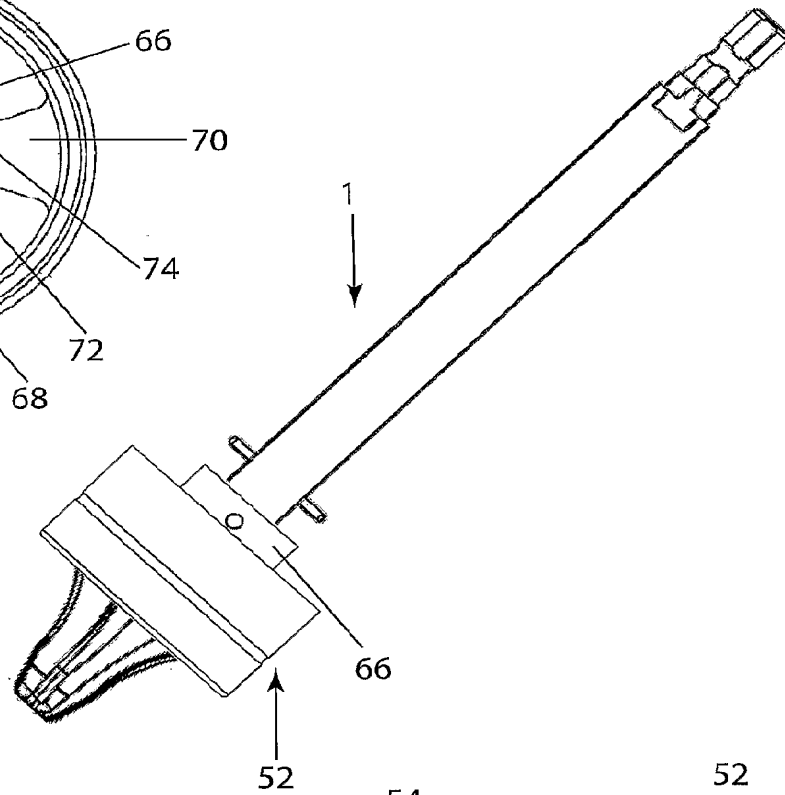


Figure 6

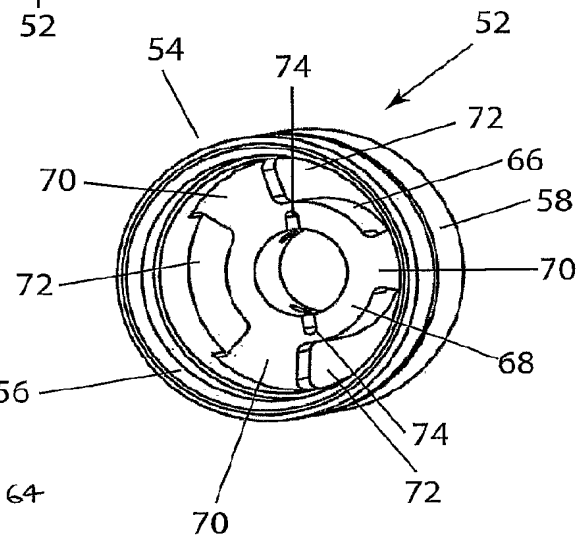
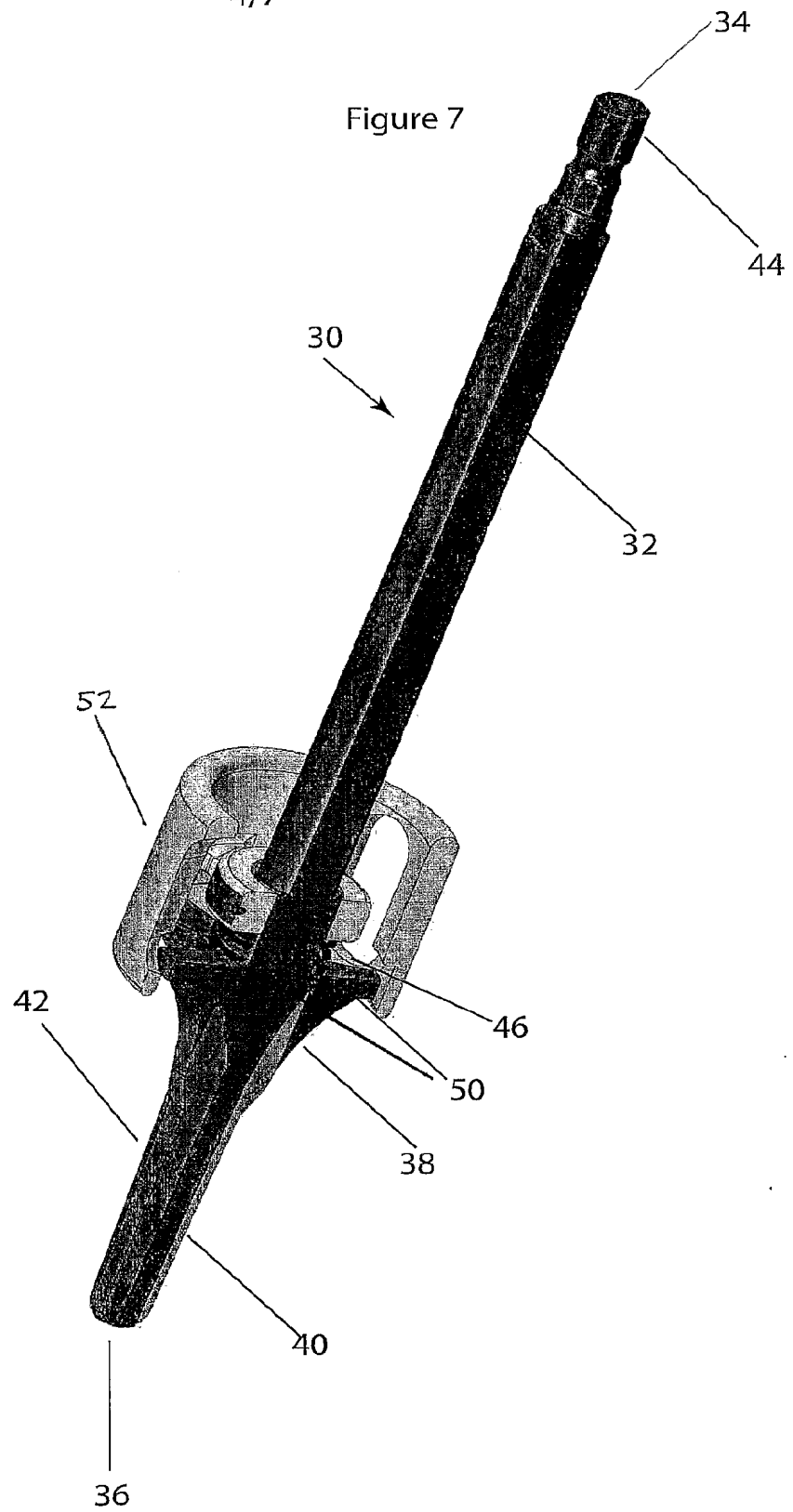
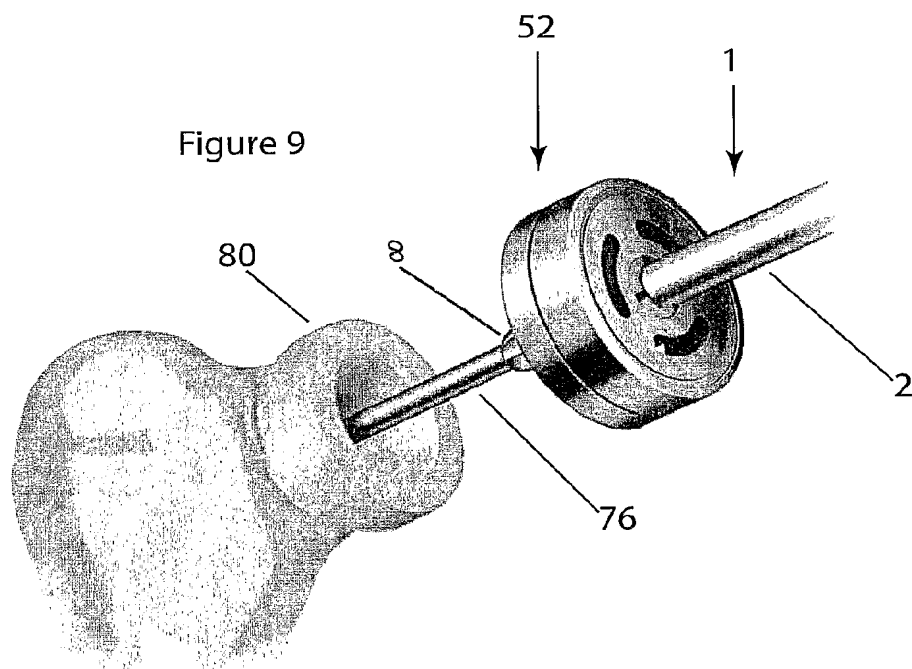


Figure 4

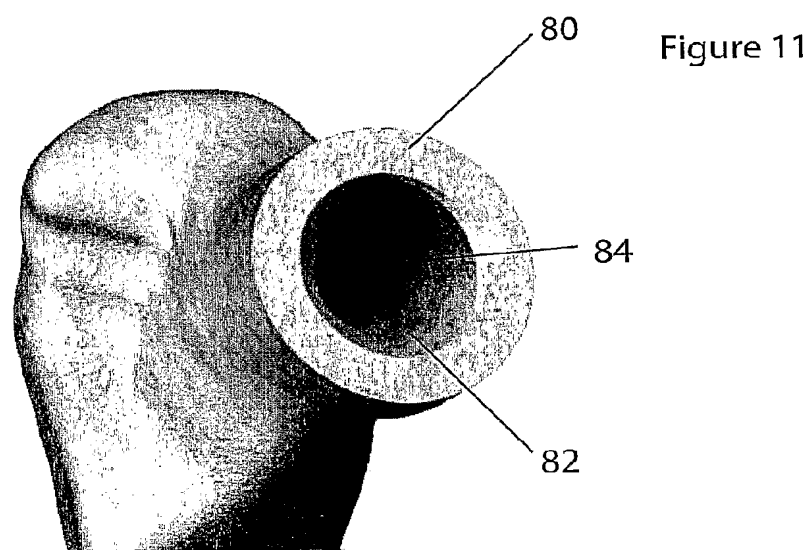
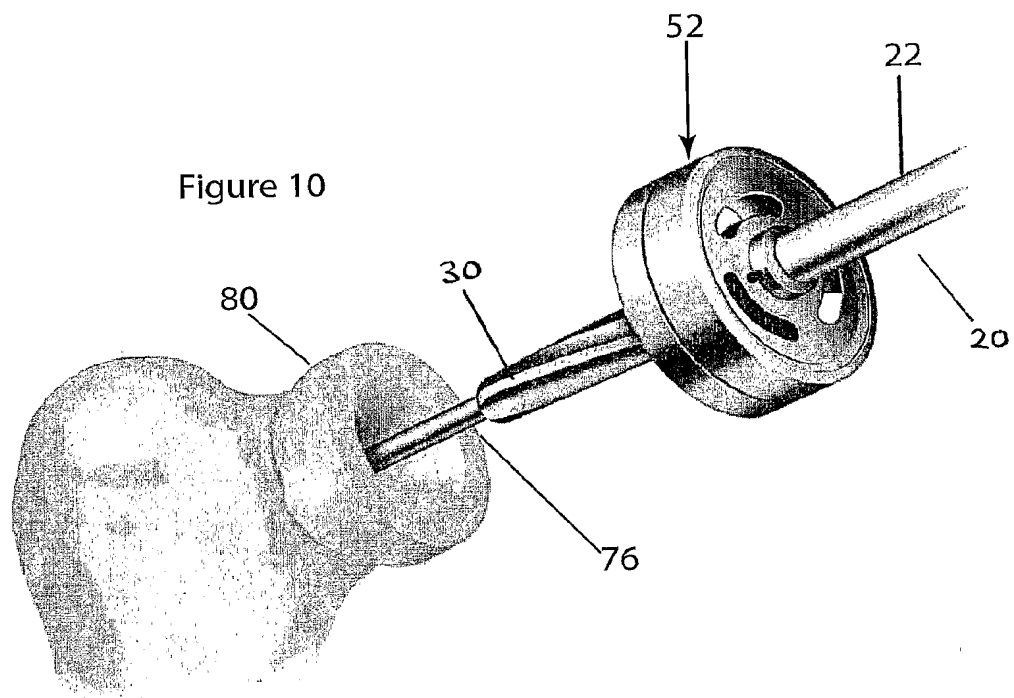
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Figure 7





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Figure 12

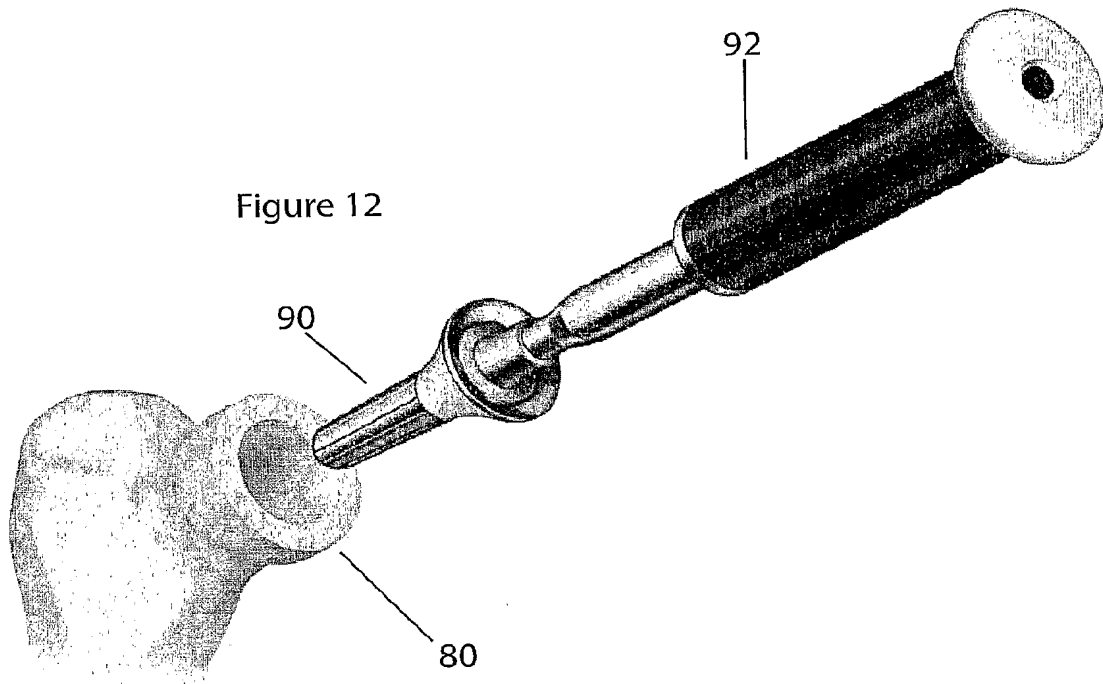


Figure 13

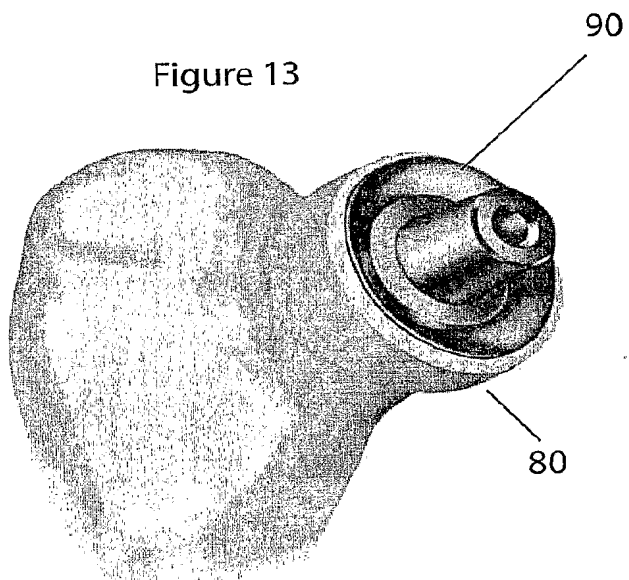
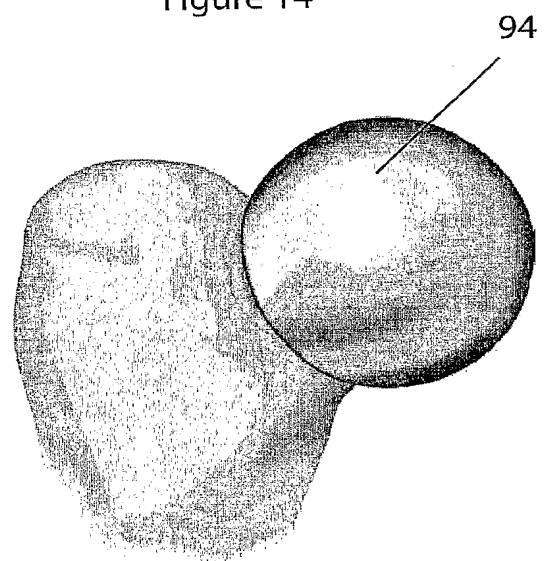


Figure 14



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0617134.2 31 August 2006 (31.08.2006) GB
- (71) **Applicant (for all designated States except US):** SMITH & NEPHEW PLC [GB/GB]; 15 Adam Street, London, WC2N 6LA, United Kingdom (GB).
- (72) **Inventor; and**
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- (74) **Agent:** CONNORS, Martin; Smith & Nephew Research Centre, York Science Park, Heslington, York, YO10 5DF, United Kingdom (GB).
- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

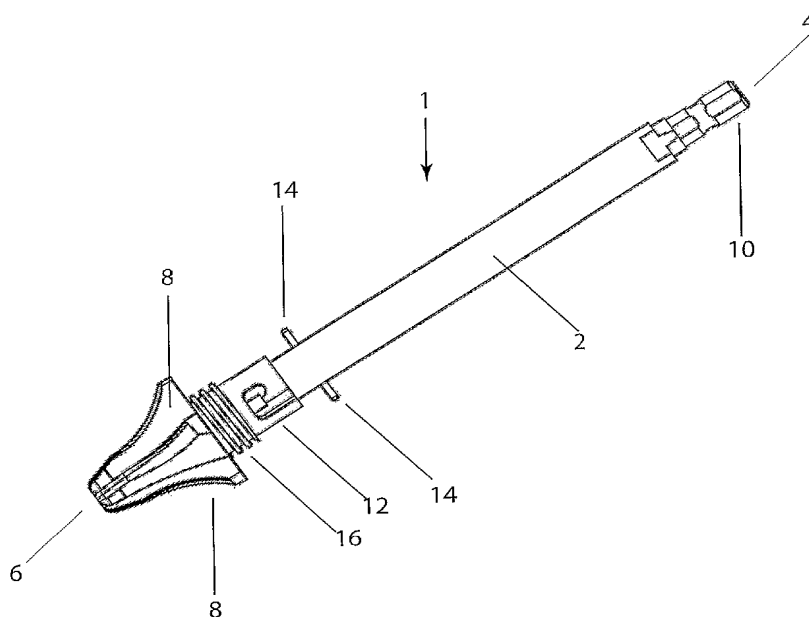
- (84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) **Title:** MEDICAL DEVICE



(57) **Abstract:** A cutting tool (1) for cutting bone, comprising: a body (2) having a proximal end (4) and a distal end (6); and at least one primary cutting surface (8) disposed at the distal end (6); wherein the at least one primary cutting surface (8) is shaped so that when, in use, a torque is applied to the proximal end (4) of the body (2), the at least one primary cutting surface (8) cuts a conical or frustoconical shaped cavity in the bone. A method for cutting bone using such a cutting tool (1).

WO 2008/025993 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/003296

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 A61B17/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2004/267266 A1 (DANIELS DAVID WAYNE [US] ET AL) 30 December 2004 (2004-12-30) paragraphs [0069] - [0075], [0086] - [0088], [0102] - [0105], [0113], [0114]; figures 6,7,21,22,25	1-14, 16-18 15
X A	GB 1 467 332 A (BATTIATO F) 16 March 1977 (1977-03-16) page 3, line 42 - line 61; figure 7	1-15 16-18
A	EP 1 201 191 A (STRYKER TECHNOLOGIES CORP [US]) 2 May 2002 (2002-05-02) paragraph [0021]; figure 8	1-18
A	US 5 957 925 A (COOK KEVIN S [US] ET AL) 28 September 1999 (1999-09-28) column 3, lines 2-7; figure 2	1-18
	----- -/-	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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- * & * document member of the same patent family

Date of the actual completion of the international search

11 June 2008

Date of mailing of the international search report

24/06/2008

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/003296

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 202 13 728 U1 (MERETE MEDICAL GMBH [DE]) 5 December 2002 (2002-12-05) page 1, line 1 - page 3, line 16; figures 5,6	19,20, 25-27,29
A	----- US 4 896 663 A (VANDEWALLS MARK V [US]) 30 January 1990 (1990-01-30) abstract; figures 1-6	19-29
A	----- EP 0 865 776 A (BURKE DENNIS W [US]) 23 September 1998 (1998-09-23) abstract	19-29

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 30-37

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Continuation of Box II.2

Claims Nos.: 38-42

Claims 38-42 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not defined. Said claims contain references to the description and the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here. No opinion is therefore established regarding said claims.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/003296

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 30-37
because they relate to subject matter not required to be searched by this Authority; namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☒ Claims Nos.: 38-42
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18.

A cutting tool with conically shaped primary and secondary cutting surfaces at the distal end of a cannulated shaft.

2. claims: 19-29

An alignment device for a cutting tool comprising attachment means and a bone engaging surface to limit the cutting depth of the cutting tool, a system comprising a conically shaped cutting tool and said alignment device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2007/003296

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 2004267266	A1	30-12-2004	US 2007162033	A1	12-07-2007
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EP 1201191	A	02-05-2002	NONE		
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DE 20213728	U1	05-12-2002	NONE		
US 4896663	A	30-01-1990	NONE		
EP 0865776	A	23-09-1998	CA 2231716	A1	12-09-1998
			DE 69814714	D1	26-06-2003
			DE 69814714	T2	25-03-2004
			JP 4012618	B2	21-11-2007
			JP 10272148	A	13-10-1998